



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0557]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Postmarket Surveillance of Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review - Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0449. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360l) authorizes FDA to require a manufacturer to conduct postmarket surveillance (PS) of any device that meets the criteria set forth in the statute. The PS regulation establishes procedures that FDA uses to approve and disapprove PS plans. The regulation provides instructions to manufacturers, so they know what information is required in a PS plan submission. FDA reviews PS plan submissions in accordance with 21 CFR 822.15 through 822.19 of the regulation, which describe the grounds for approving or disapproving a PS plan. In addition, the PS regulation provides instructions to manufacturers to submit interim and final reports in accordance with 21 CFR 822.38. Respondents to this collection of information are those manufacturers that require PS of their products.

In the *Federal Register* of May 27, 2022 (87 FR 32169), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

21 CFR Part/Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
§§ 822.9 and 822.10; PS submission	5	1	5	120	600
§ 822.21; Changes to PS plan after approval	9	1	9	40	360
§ 822.28; Changes to PS plan for a device that is no longer marketed	1	1	1	8	8
§ 822.29; Waiver	0	0	0	40	0
§ 822.30; Exemption request	0	0	0	40	0
§ 822.38; Periodic reports	17	3	51	40	2,040
Total					3,008

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Explanation of Reporting Burden Estimate: The burden captured in table 1 is based on the data from FDA's internal tracking system. 21 CFR 822.26, 822.27, and 822.34 do not constitute information collection subject to review under the PRA because it entails no burden other than that necessary to identify the respondent, the date, the respondent's address, and the nature of the instrument (see 5 CFR 1320.3(h)(1)).

Table 2.--Estimated Annual Recordkeeping Burden¹

21 CFR Part/Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
§ 822.31; Manufacturer records	5	1	5	20	100
§ 822.32; Investigator records	15	1	15	5	75
Total					175

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Explanation of Recordkeeping Burden Estimate: FDA expects that at least some of the manufacturers will be able to satisfy the PS requirement using information or data they already have. For purposes of calculating burden, however, FDA has assumed that each PS order can only be satisfied by a 3-year clinically based surveillance plan, using three investigators. These estimates are based on FDA's knowledge and experience with PS.

We have adjusted our burden estimate, which has resulted in a decrease to the currently approved burden. Our estimated burden for the information collection reflects an overall decrease of 4,780 hours and a corresponding decrease of 145 responses. We believe these adjustments more accurately reflect the current number of requests associated with postmarket surveillance of medical devices.

Dated: November 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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